UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01-12257-PBS** **Subcategory Case No. 06-11337**
THIS DOCUMENT RELATES TO: *State of California, ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.* Case No: 1:03-cv-11226-PBS	**Judge Patti B. Saris** **Magistrate Judge Marianne B. Bowler**

PLAINTIFFS' OPPOSITION TO DEFENDANTS' JOINT BRIEF IN SUPPORT OF THEIR MOTIONS FOR PARTIAL SUMMARY JUDGMENT

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PRELIMINARY STATEMENT AND GENERAL RESPONSE TO DEFENDANTS' STATEMENT OF FACTS

Pursuant to Rule 56 of the Federal Rules of Civil Procedure and Local Rule 56.1, Plaintiffs, the State of California and Ven-A-Care of the Florida Keys, Inc. ("Plaintiffs"), submit this Memorandum in Opposition to the Joint Motion for Partial Summary Judgment submitted by Dey, L.P. and Dey, Inc. ("Dey"), Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. ("Mylan"), and Sandoz Inc. ("Sandoz") (collectively, "Defendants")

In what has become a familiar one-note refrain from AWP-fraud manufacturer defendants, Defendants' summary judgment Joint Brief is confined to a series of arguments which, in essence, blame California for not having earlier grasped the fact and extent of Defendants' fraudulently inflated AWPs. Every proffered "Statement of Fact" focuses on California, Medi-Cal, Ven-A-Care's ("VAC's") complaint on behalf of California, the federal government, other state Medicaid programs, or unrelated government litigation surrounding statutory changes. This succession of red herrings is accompanied by a studied disregard of the facts bearing on Defendants' conduct in reporting and marketing fraudulently inflated AWPs, and an equally apparent indifference toward the other key issues of law characterizing the instant critical stage, including the absence of any recognition whatsoever of any Defendant's (a) obligations toward publicly funded public health programs, (b) liability, and (c) potentially very serious damages and, equally if not more importantly, penalties. Nowhere do Defendants even fleetingly acknowledge the fact that Medi-Cal reimbursed providers based on Defendants' fraudulently inflated AWPs. Although Defendants insist it is the array of facts characterizing California's dogged and proactive (if imperfect) efforts to deal with the pernicious effects of Defendants' false AWPs which doom the State's case, Defendants fail to demonstrate that there

are no material facts in dispute regarding the question of whether California's efforts to deal with Defendants' fraud amounted to an approval or ratification of Defendants' unlawful conduct.

Moreover, nowhere do the Defendants, through declaration or testimony, demonstrate that reporting grossly inflated AWPs was in any way consistent with any official policy of the State of California. Despite their strident insistence regarding what the California Department of Health Care Services ("DHCS") (which administers the Medi-Cal program) and the California Legislature allegedly "knew," Defendants cannot reasonably expect this Court to find that Defendants did *not* know that reporting fraudulently inflated AWPs was a violation of codified California regulatory and statutory standards, when they themselves do not affirmatively say as much. In other words, while Defendants spill much ink in argument to the effect that California deliberately allowed itself to be defrauded, they cannot bring themselves to state, simply and without qualification, that throughout the relevant time period they believed that their grossly inflated AWPs were consistent with California law.

Recognizing the infirmities of their government knowledge defense, Defendants also resort to a causation argument. They claim, in essence, that California's use of their inflated AWPs was both necessary and required for beneficiary access, and as such constitutes an intervening event that severs the causal nexus between Defendants' fraudulent price inflation and Medi-Cal's overpayments premised thereon. Stripped to its essential non sequitur, Defendants' argument is that "because California did not act earlier to counter Defendants' false AWPs, it must have intended to allow such conduct."

This argument, however, ignores two fundamental facts. First, notwithstanding that Medi-Cal was properly concerned with ensuring adequate access for program beneficiaries through sufficient provider participation, that fact neither vitiates causation, nor supports

Defendants' claim that Medi-Cal knowingly and deliberately elected to pay mega-spreads on Defendants' drugs.

Second, the reality is that government works slowly—sometimes by design. A complex and multi-faceted *government reimbursement* (as opposed to a *government purchasing*) program such as Medi-Cal has many stakeholders, is beholden to due process constraints, and is poorly equipped to adjust quickly or even effectively to a sophisticated, widespread and opaque industry practice. This is particularly true of an industry practice focused on deliberately inflating the AWPs of select drug NDCs, especially when Medi-Cal's formulary includes approximately 26,000 NDCs. (*See* CA SOAF Dey 11). Defendants' arguments to the contrary notwithstanding, the government's gradual adaptation to manufacturers' dubious price-reporting practices does not amount to approval or ratification. *See In re Pharmaceutical Industry Average Wholesale Price Litigation*, 582 F.3d 156, 171 (1st Cir. 2009) ("On balance, we read the legislative history and statutory context [concerning Congress's response to drug manufacturers' practice of reporting false AWPs] to be one of slow adaptation to shadowy industry practices, not ratification of them.").

The relevant regulatory history shows that when DHCS reduced its reimbursement rate in 1989 to AWP-5%, the program was doing its best to arrive at a rate that, on a program-wide basis, represented the best estimate of providers' acquisition costs for covered drug products. AWP has at all times been defined as one of several reference prices by which Medi-Cal would estimate the acquisition cost of drug products—i.e., a statutorily defined reference indicating prices generally and currently paid by providers—under California's "lowest of" reimbursement methodology. (CA SOAF Defs. ¶¶ 18-19.) Similarly, there is nothing in the record that supports the idea that, when the California Legislature subsequently reduced the reimbursement rate by

twice increasing the statutory discount off of AWP for AWP-based reimbursement, it intended to endorse Defendants' inflated spreads.

Medi-Cal's reliance on Defendants' AWPs during the relevant period (1994-2004) in fact accentuates, not vitiates, the causal nexus between Defendants' conduct and the harm it caused California. As this Court has previously explained in analogous circumstances:

> Defendant argues that Relator has not stated a claim because he has not accounted for the independent actions of the physicians who wrote the off-label prescriptions and the pharmacists who accepted and filled the off-label prescriptions. In other words, Defendant argues that—as a matter of law—Relator's allegations cannot establish the causation requirement of the FCA because the actions of these professionals were an intervening force that breaks the chain of legal causation. Under black letter law, however, such an intervening force only breaks the causal connection when it is *unforeseeable*. Accord D. Dobbs, et al., Prosser and Keeton on Torts § 44, at 303-04 (5th ed. 1984) ("The courts are quite generally agreed that [foreseeable intervening forces] will not supersede the defendant's responsibility."); Restatement (Second) of Torts § 443 (1965) ("The intervention of a force which is a normal consequence of a situation created by the actor's … conduct is not a superseding cause of harm which such conduct has been a substantial factor in bringing about."). In this case, when all reasonable inferences are drawn in favor of the Relator, the participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud.

United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 52-53 (D. Mass. 2001) (internal citations omitted) (emphasis added); s*ee also United States ex rel. Grubbs v. Ravikumar Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) ("The doctor can cause the fraud by putting a fraudulent record into a system that he knows will ministerially crank out a fraudulent bill to the Government."). Defendants ignore the fundamental reality that the Medi-Cal reimbursement methodology and governing rate during the relevant period were established pursuant to a formal rulemaking proceeding in 1989, and were then subsequently modified by statute. Defendants further ignore the relevant regulatory and statutory record, instead relying on OIG reports and

agency e-mails that they argue show formal "government knowledge", but in reality have little or no relevance to the governing reimbursement standards. To this end, Defendants commit two pages to discuss various reports during the 1970s and mid-1980s, well before the relevant period, but relegate to one sentence the fact that in September 1989, DHCS, in a formal rulemaking proceeding, revised its reimbursement rate to AWP-5%. In making that change, DHCS expressly concluded that, in setting its reimbursement rate, "the State must come as close as possible to the actual acquisition cost. The AWP-5% program is the State's best estimate of this cost." (CA SOAF Defs. ¶ 19.)

Defendants' strained reliance on the Ninth Circuit's decision in *Orthopaedic Hospital v. Belshe*, 103 F.3d 1491 (9th Cir. 1997), *cert. denied*, 422 U.S. 104 (1998) is misplaced. In *Orthopaedic Hospital*, the Ninth Circuit enjoined DHCS from reducing its hospital reimbursement rates in the absence of a study that ensured that any revisions to those rates were consistent with Medicaid's goals of efficiency, economy, quality service, and access. *Id*. at 1500. The real significance of *Orthopaedic Hospital* is that the program was unable to reduce its pharmacy rates until it completed such a study—regardless of statements in OIG reports, or the general beliefs of some agency personnel that AWPs were increasingly inflated.[1] In 1999, the

[1] One disturbing theme, which thoroughly permeates Defendants' self-serving version of events over the relevant period (1994-2004), is the unsavory position they implicitly convey regarding the extent of *their* obligations to Medi-Cal and Medicaid (i.e., state and federal governments—"the Government") when an OIG or similar report was issued. *No* Defendant *ever* attempted to contact the California Department of Health Care Services to discuss the implications to the public fisc of the inflated price reporting studied in *any* OIG report. (CA SOAF Defs. ¶ 29.) In the Defendants' skewed understanding of the public health world regarding "Government vs. Defendant" obligations toward the public fisc where their products are involved, Defendants obviously believe they can report deliberately inflated AWPs with impunity. This disturbing perception of the drug industry's responsibilities toward government-administered public health programs, which pay billions of dollars for the industry's drugs every year, spawns Defendants' next fiction: When, in response to the industry's fraud, the Government expends the public resources necessary to achieve some general understanding of the extent and impact of Defendants' deliberately inflated AWPs, and documents that effort in an OIG or similar federal or state report—such as California's publicly funded $400,000-$500,000 California Myers and Stauffer reports (see CA SOAF Defs. ¶ 32)—the Government is thereby deemed to have (a) conveyed an acceptance of the unlawful conduct that triggered the Government's investigation, while simultaneously (b) surrendering all recourse to legal remedies under applicable False Claims Act statutes. Under this perverse logic, from a litigation perspective, the Government would have been far better

California Legislature directed that DHCS do such a study, which was ultimately completed in August 2002. (CA Resp. Defs. SOF ¶¶ 41-42.) Consistent with the holding in *Orthopaedic Hospital* and the fact that it was conducting a rate study, DHCS opposed a rate reduction in 2000 because, among other reasons, a proper rate study had not been completed. (Defs. Jt. SOF ¶ 36.)

Defendants' reliance on the Myers & Stauffer reports fares no better. The Legislature did not have the benefit of those reports when crafting the 2002 statutory reduction in AWP-based reimbursement from AWP minus 5% to minus 10%. In 2004, the Legislature used the Myers & Stauffer reports in crafting a comprehensive rework of the Medi-Cal reimbursement formula, including a reduction in AWP-based reimbursement from minus 10% to minus 17%.

Finally, neither VAC's complaints, nor any of the numerous analytical or investigatory actions undertaken by California regulatory and legislative bodies subsequent to VAC's complaints or following the State's intervention in those complaints, are pertinent to a causation determination. VAC's complaints provided initial and miscellaneous pieces of information about selected companies gaming the system, but neither justified or compelled a wholesale revision to the reimbursement methodology.

Notwithstanding Defendants' lengthy recitation of the history of the efforts undertaken by various California governmental entities to identify and react to Defendants' price manipulations—manipulations of a price that had and continues to have no significance to the drug industry beyond serving as a benchmark for third party drug payors, most significantly government public health program payors—the only questions before this Court are whether (a) Defendants reported false AWPs, and (b) they did so knowingly, as that term is used in the

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served to have stuck its head in the sand and never make *any* attempt to investigate or understand the parameters of Defendants' AWP fraud, since each and every study, report, proposal or legislative initiative undertaken by the Government to study or manage the consequences of fraud could be twisted into a "government knowledge" defense. This, of course, is precisely what the Defendants have attempted here.

California False Claims Act, CAL. GOV'T CODE §§ 12650 *et seq.* ("CA FCA"). Plaintiffs' motion for partial summary judgment makes the case for affirmative responses to both questions. Certainly, there is ample evidence documenting California's efforts to restructure and adjust its reimbursement system in a series of attempts to manage the programmatic implications of Defendants' fraud, even if the complete and precise contours of that fraud were not fully understood until discovery in this action was completed. There is *no* evidence, however, that California ever ratified or approved of Defendants' price reporting practices or their grossly inflated AWPs.

LEGAL STANDARD FOR SUMMARY JUDGMENT

"Summary judgment is appropriate when the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." *Barbour v. Dynamics Research Corp.*, 63 F.3d 32, 36-37 (1st Cir. 1995), quoting Fed. R. Civ. P. 56(c). "To succeed [in a motion for summary judgment], the moving party must show that there is an absence of evidence to support the nonmoving party's position." *Rogers v. Fair*, 902 F.2d 140, 143 (1st Cir. 1990). In assessing whether such showing has been made, the Court must "view the facts in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor." *Barbour*, 63 F.3d at 36.

ARGUMENT

I. AS A MATTER OF LAW, DEFENDANTS CANNOT AVOID LIABILITY FOR CAUSING CALIFORNIA'S DAMAGES THROUGHOUT THE RELEVANT TIME PERIOD.

Defendants argue that, as a matter of law, their reporting of grossly inflated AWPs did not cause the State any damages from 1997 to 2004. (Defs. Jt. SJ Br. 14.) In making this

argument, Defendants apparently ignore the fact that damages are not a necessary element of the State's claims under the CA FCA. CAL. GOV'T CODE § 12651(a); *State v. Altus Finance, S.A.*, 36 Cal. 4th 1284, 1299 (2005). More importantly, Defendants also appear to ignore the undeniable fact that Medi-Cal directly relied on the grossly inflated AWPs they reported in determining how much to reimburse providers for dispensing the drug products at issue. Even allowing Defendants the benefit of a 25% margin before calculating any damages, Medi-Cal's reliance on those inflated AWPs caused hundreds of millions of dollars in overpayments for Defendants' products. (CA SOAF Defs. ¶ 1.)

Defendants' argument is based on a torturous misapplication of the Ninth Circuit's decision in *Orthopaedic Hospital*, and on the incredible assertion that Medi-Cal decided to reimburse providers for the Subject Drugs at spreads of over 2000% because, "after careful study and extensive surveys," the State deemed such payments "necessary to ensure that the pharmacy benefit under the Medi-Cal program was administered efficiently and economically…." (Defs. Jt. SJ Br. 14-15.) Not only is that assertion unsupported by any reasonable reading of the record, but, as California made clear in its cross-motion for partial summary judgment, Defendants' and other manufacturers' reporting of grossly inflated AWPs directly caused Medi-Cal to reimburse pharmacists in excessive amounts, and cost Medi-Cal hundreds of millions of dollars that should have been spent in providing care to the State's needy. (CA SOAF Defs. ¶¶ 1-2, 12-14.)

A. While California Has Suffered Substantial Damages Resulting from Defendants' Grossly Inflated AWPs, Plaintiffs Need Not Demonstrate Damages Under the CA FCA

1. Plaintiffs Need Not Demonstrate Damages Under the CA FCA.

Initially, it is important to note that, while the State has sustained substantial damages from Defendants' acts, damages are not an essential element of the State's claims under the CA FCA. That statute, like the Federal Act, proscribes the presentment of false claims regardless of

whether the State sustains any damages as a result. CAL. GOV'T CODE § 12651(a); *see United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Group, Inc.*, 400 F.3d 428, 445-46 (6th Cir. 2009) (the FCA imposes liability "upon presentment of a false or fraudulent claim, rather than actual payment on that claim"); *State v. Altus Finance*, 36 Cal. 4th at 1299 (CA FCA "authorizes civil penalties for attempts to misappropriate public funds that were not in fact completed by payment from the treasury"). Indeed, similar to the Federal Act, the CA FCA prescribes civil penalties of up to $10,000 for each false claim caused by Defendants, irrespective of whether California suffered any actual damages. *Id*. Hence, even if Defendants' damages argument had merit—which it does not—that argument would not be a basis for summary judgment as to any of Plaintiffs' claims for relief: There are over 24 million actionable false claims at issue in this case. (*See* Paul Decl. Exs. 24-26.)

2. Defendants' Grossly Inflated AWPs Caused California to Suffer Hundreds of Millions of Dollars in Damages.

More significantly, it is clear that Defendants' reporting of grossly inflated AWPs caused substantial damages to Medi-Cal; at a bare minimum, there is a factual question in that regard. The governing law is not in substantial dispute: California is entitled to recover "three times the amount of damages which the state . . . sustains because of" Defendants' acts. CAL. GOV'T CODE § 12651(a). As the California Court of Appeal noted in *Fassberg Const. Co. v. Housing Authority of City of Los Angeles*, 152 Cal. App. 4th 720 (2007), "[t]he ordinary measure of damages under California law for breach of an obligation not arising from a contract is the amount that will compensate for all of the loss or harm proximately caused by the breach." *Id*. at 749, citing CAL. CIV. CODE §§ 3333 & 3282.[2] That standard is handily met here.

[2] There is a dispute among the circuits as to whether the government must establish "proximate cause" or only a more relaxed "but for" standard of causation in actions under the FCA. The Sixth, Seventh, and Ninth Circuits apply a pure "but for" causation test, in that "a demonstration that the government would not have [paid the claim]

Pursuant to the applicable statutes and regulation, at all relevant times Medi-Cal was required to reimburse pharmacy providers for the cost of a drug product they dispensed to Program beneficiaries at the lesser of several amounts, one of which was the product's Estimated Acquisition Cost ("EAC"). CAL. WELF. & INST. CODE §§ 14105.46 (eff. Sept. 30, 2002 – August 15, 2004); 14105.45 (eff. Aug. 16, 2004); CAL. CODE REGS. tit. 22, § 51513. EAC, in turn, was set at the products' AWP as published by the Department's primary reference source, First DataBank ("FDB"). *Id*. Because Defendants reported AWPs that were grossly inflated over any reasonable estimate of actual average wholesale prices, and those AWPs were then published by FDB and used by Medi-Cal as part of its reimbursement calculations, Defendants directly and proximately caused Medi-Cal to suffer millions of dollars in damages.[3] (CA SOAF Defs. ¶¶ 1-4.)

As this Court found in the related Massachusetts case:

> Here, the defendants reported false prices to MassHealth via the publishing compendium knowing that pharmacies would present claims to MassHealth which will be reimbursed based on a formula that utilizes the inflated price to determine the appropriate reimbursement amount. Thus, although the manufacturers do not themselves submit claims to the Commonwealth, and the claims do not themselves contain WACs or AWPs, the claims here were predicated on an underlying fraudulent pricing scheme. The

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'but for' the false statement is sufficient to establish the causal relationship between the false claim and the government's damages necessary to permit recovery under the False Claims Act." *United States v. First National Bank of Cicero*, 957 F.2d 1362, 1374 (7th Cir. 1992); *see also United States v. Ekelman & Associates, Inc.*, 532 F.2d 545, 551 (6th Cir. 1976); *United States v. Eghbal, 475 F. Supp. 2d 1008, 1014-15* (C.D. Cal. 2007) (citing Ninth Circuit cases). The Third, Fifth, and D.C. Circuits appear to require that the subject matter of the false statement be the source of the government's loss (which has been described as a "proximate cause" standard). *United States v. Hibbs*, 568 F.2d 347, 351 (3d Cir. 1977); *United States v. Miller*, 645 F.2d 473, 476 (5th Cir. 1981). Arguably, the looser "but for" standard should apply under the CA FCA given the express legislative dictate that the Act "shall be liberally construed and applied to promote the public interest." CAL. GOV'T CODE § 12655(c). But this Court need not reach that issue. Under any conceivable standard, Defendants' reporting of grossly inflated AWPs caused damages to Medi-Cal, given the fact that Medi-Cal was required by governing law to estimate providers' acquisition costs based on those AWPs. Further, as noted by Former Chief Deputy Director of Health Care Services Stan Rosenstein, California relies upon accurate reporting of AWPs, and but for the false reporting of AWPs by manufacturers, California would have saved hundreds of millions of dollars. (CA SOAF Defs. ¶¶ 12-13.)

[3] This direct causal connection between Defendants' decision to report inflated AWPs and the damages suffered by California is illustrated by demonstrative charts submitted herewith. (CA SOAF Defs. ¶ 3.)

> defendants are thus chargeable with causing false claims to be presented to the Commonwealth**.**

Massachusetts v. Mylan Labs., 608 F. Supp. 2d 127, 145 (D. Mass. 2008) (citations and quotations omitted) ("*Mylan Labs.*"). *See also In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 498 F. Supp. 2d 389, 400 (D. Mass. 2007):

> Indeed, Dey's publication of false price data, which involves the regular quarterly republication of false AWP figures with knowledge that these figures would be used to set reimbursement figures for subsequent claims, is distinguishable from the case in [*United States v. Bornstein*, 423 U.S. 303, 312 (1976)] where the submission of multiple claims "was, so far as [defendant] was concerned, wholly irrelevant completely fortuitous and beyond [defendant's] knowledge or control." *Bornstein*, 423 U.S. at 312. As such, in this case a claim accrued each time a false claim was presented. *See* [*United States v. Rivera*, 55 F.3d 703, 707 (1st Cir. 1995)].

The same rationale applies with equal force here.

B. Defendants Have Failed to Support their Argument that California's Overpayments Were the "Direct and Proximate Result" of Medi-Cal's Deliberate Attempt to Comply with the Medicaid Act.

1. Defendants' Arguments Related to Orthopaedic Hospital.

Defendants contend that, as a matter of law, California's damages were not the result of their false and fraudulent AWPs, but the result of California's alleged "deliberate execution" of its obligation to set reimbursement rates in a manner consistent with the holding of *Orthopaedic Hospital*, in which the court considered the proper interpretation of Section 30(A) of the Medicaid Act[4] as applied to proposed changes to hospital reimbursement rates by Medi-Cal. In relevant part, Section 30(A) provides that state Medicaid plans must reimburse providers at rates that are "consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." In

[4] 42 U.S.C. § 1396a(a)(30)(A).

Orthopaedic Hospital, the Ninth Circuit interpreted Section 30(A) to mean that when establishing reimbursement rates for hospital services, Medi-Cal must set rates that "bear a reasonable relationship to efficient and economical hospitals' costs of providing quality services, unless the Department shows some justification for rates that substantially deviate from such costs." *Id*. at 1496. To comply with this mandate, Medi-Cal "must rely on responsible cost studies, its own or others', that provide reliable data as a basis for its rate setting." *Id*.

Defendants observe that in 1999, two years after *Orthopaedic Hospital* was decided, the California legislature directed DHCS to "conduct a study of the adequacy of Medi-Cal pharmacy reimbursement rates, including the cost of providing prescription drugs and services." (Defs. Jt. SJ Br. 7; CA SOAF Defs. ¶ 5.) DHCS thereafter commissioned the accounting firm of Myers & Stauffer LC to complete the study, ultimately published on August 23, 2002. (Robben Decl. Ex. 33-34, 35 at 93.) According to Defendants, with the Myers & Stauffer reports in hand, "California now had the 'proper rate study' required by *Orthopaedic Hospital* to set a reimbursement rate that would be 'consistent with efficiency, economy, and quality of care [] sufficient to enlist enough providers'" and that "California proceeded to do just that, first in December of 2002, and again in September of 2004." (Defs. Jt. SJ Br. 11.) Based on the foregoing, Defendants argue, they cannot be liable for their false price reporting practices because California cannot demonstrate that any of its damages accrued "because of the act of [Defendants]." (Defs. Jt. SJ Br. 15.) As demonstrated below, however, Defendants' argument—a naked attempt to dissociate their fraudulently inflated AWPs from Medi-Cal's overpayments—is meritless.

2. Defendants' Concessions with Respect to California's Claims.

As a preliminary matter, it is worth noting the obvious. The relevant time period alleged in Plaintiffs' action begins in 1994 and extends through 2004. Regardless of when they were

commissioned, the Myers & Stauffer reports were not issued until August 23, 2002—less than 18 months before the conclusion of Plaintiffs' alleged damages. (Robben Decl. Ex. 1 at ¶ 43; Robben Decl. Ex. 35 at 93.) If, as alleged by Defendants, it was only upon the publication of the Myers & Stauffer reports that "California now had the 'proper rate study' required by *Orthopaedic Hospital* to set a reimbursement rate that would be 'consistent with efficiency, economy, and quality of care [] sufficient to enlist enough providers,'" (Defs. Jt. SJ Br. 11) then Defendants appear to concede that California could *not* have affirmatively done so in a manner consistent with *Orthopaedic Hospital* before then. Given Defendants' own reasoning, therefore, the overpayments California made until at least August 23, 2002, when the reports were issued, simply could not have been the "direct and proximate result of California's *deliberate execution* of its legal obligation to pay reimbursement rates consistent with efficiency, economy, quality of care, and access…" as interpreted by *Orthopaedic Hospital*. (Defs. Jt. SJ Br. 18, emphasis added.)

Furthermore, Defendants' embrace of the Myers & Stauffer reports as providing California with a proper rate study that "now" allowed it to adjust rates in conformance with *Orthopaedic Hospital*, would necessarily mean that the two previous reports cited by Defendants (i.e., the 1996 HHS-OIG report and the 1977 California Dept. of Finance report) did not do so. Defendants would consequently be compelled to agree that while these previous studies may have provided Medi-Cal with a generalized suggestion of inaccurately inflated AWPs for some manufacturer's drugs, as a matter of law (and as a matter of Defendants' own argument), the same studies could not have formed the basis for any degree of "knowledge" sufficient to raise a successful affirmative defense for Defendants.

3. Defendants Mischaracterize the Purpose of the Myers & Stauffer Reports.

Much of Defendants' argument is premised on their inflation of the Myers & Stauffer reports into documents of purportedly dispositive significance. In stating that the Myers & Stauffer reports provided Medi-Cal with "a proper rate study" (Defs. Jt. SJ Br. 11) for the purpose of changing provider reimbursement rates, it is clear that Defendants have mischaracterized their import in an effort to justify the indefensible spreads on their drugs. The Myers & Stauffer reports were the result of California Senate Bill 393, which was chaptered in October 1999. (CA SOAF Defs. ¶ 5; Robben Decl. Ex. 33 at 3.) Specifically, SB 393 provided that "[t]he bill would also require the State Department of Health Services to conduct a study of the adequacy of Medi-Cal pharmacy reimbursement rates, including the cost of providing prescription drugs and services."[5] (*Id.*) While the Myers & Stauffer reports may have been relied upon to some extent by the California Legislature to justify a rate change in 2004, the plain language of SB 393 makes clear that the reports were never intended to identify the specific rate at which Medi-Cal should reimburse providers in light of Section 30(A) as interpreted by *Orthopaedic Hospital*. Rather, the reports were commissioned to simply study the adequacy of the then current rates in relation to dispensing costs incurred by providers. Accordingly, the reports did not provide a definitive answer concerning which rate (or rates) California should set for prescription drug reimbursement vis-à-vis *Orthopaedic Hospital*; instead, they merely provided California with a better understanding of provider dispensing costs and unambiguously confirmed the hyper-inflated nature of the manufacturers' reported AWPs.

[5] As a result of SB 393, the California Business and Professions Code was amended to provide that "[t]he State Department of Health Services shall conduct a study of the adequacy of Medi-Cal pharmacy reimbursement rates including the cost of providing prescription drugs and services." CAL. BUS. & PROF. CODE § 4426. (CA SOAF. Defs. ¶ 5.)

Moreover, contrary to the Defendants' Suggestion, the Myers & Stauffer reports never purported to identify *the floor* on reimbursement that would ensure payments that were consistent with efficiency, economy, and quality of care, sufficient to enlist enough providers. (Defs. Jt. SJ Br. 11) Rather, the reports simply demonstrated that certain manufacturers, Defendants among them, were publishing AWPs that had no reasonable relationship to the actual acquisition cost for the NDCs identified in the study. For instance, the Myers & Stauffer reports compare Mylan's Piroxicam 20mg capsule's AWP of $2.6391 against its average cost of acquisition of .0339 cents for a spread on ingredient costs of $2.61—i.e., a spread percentage of 7685%. (Robben Decl. Ex. 34 at Ex. 5; CA SOAF Defs. ¶ 6.) Such a spread might very well cover the providers' cost of dispensing the drug and might also ensure provider participation as required by *Orthopaedic Hospital*. However, this information alone says nothing about what discount from AWP was appropriate so as to both comply with *Orthopaedic Hospital* and remain consistent with the Program's interests in preserving the public fisc; it simply makes the obvious point that Mylan, again, was reporting an AWP for Piroxicam 20mg capsules, which in no way resembled its average cost of acquisition by providers.

Therefore, the Myers & Stauffer reports certainly support Plaintiffs' claim that Defendants caused the submission of false claims to Medi-Cal. However, because of the reports' limited applicability to setting Medi-Cal drug reimbursement rates, they offer no support for Defendants' argument that the overpayments resulting from Defendants' fraudulent prices were the "direct and proximate result of California's deliberate execution of its legal obligation to pay reimbursement rates consistent with efficiency, economy, quality of care, and access…." (Defs. Jt. SJ Br. 18.)

4. Defendants' Claim that the 2002 Change in Reimbursement was the Result of the 2002 Myers & Stauffer Reports is Demonstrably False.

Defendants suggest that immediately upon publication of the Myers & Stauffer reports, California was required to make fundamental changes in its reimbursement methodology and rates. Indeed, in their moving papers, Defendants imply that it was because of the publication of the reports that, pursuant to budget trailer bill AB 442, California changed prescription drug reimbursement rates from AWP-5% to AWP-10% effective December 2002. (Defs. Jt. SJ Br. 11.) However, the evidence shows otherwise.

As indicated by its legislative history, AB 442 had already been voted upon by the California Senate in June of 2002; was finally voted upon by the California Assembly on September 1, 2002, a mere week after the reports' release on August 23, 2002; and was approved by the Governor on September 30, 2002. (CA SOAF Defs. ¶ 7.) The evidence unequivocally shows, therefore, that the Myers & Stauffer reports were not considered by the full Legislature with respect to the changes in reimbursement that went into effect in December 2002.[6] This fact is verified by Chief of Medi-Cal Pharmacy Policy Kevin Gorospe, who testified that with respect to the proposed changes to reimbursement included in AB 442, the Myers & Stauffer report was "issued too late in the budget cycle process for it to be used in those decisions by the Legislature. They had already moved forward a proposal." (CA SOAF Defs. ¶ 8.)

Moreover, while Defendants convey some contempt for the pace at which California adjusted its prescription drug reimbursement policy, Plaintiffs' government policy expert Professor Marmor reminds us of the challenges faced by California, as well of the ongoing efforts undertaken by Medi-Cal and the state Legislature throughout the relevant time period

[6] Additionally, the provision addressing the reduction in reimbursement from AWP-5% to AWP-10% was identified as Section 73 of California Budget Trailer Bill AB 442, which included a total of 106 sections and extends over 150 pages in the California Legislative Digest. (CA SOAF Defs. ¶ 10.) With respect to the trailer bill, the Governor did not have line-item veto authority. (CA SOAF Defs. ¶ 9.)

(particularly from 1996 through 2002) to meet Medi-Cal's obligation to set appropriate reimbursement rates that balanced all relevant factors, including economy. As this Court has held, "[t]hat the government responded lethargically to the knowledge of fraud does not translate into approval." *Mylan Labs.*, 608 F. Supp. 2d at 151.

Professor Marmor further observes that while attempting to accomplish its mandate to provide comprehensive health care to California's most vulnerable residents, Medi-Cal was simultaneously dealing with lobbying efforts and resistance to changes concerning reimbursement policy and AWP by pharmaceutical companies; stakeholder-sponsored litigation, including *Orthopaedic Hospital* and a lawsuit filed by Defendant Dey, "which sought to enjoin First DataBank from reporting much lower and apparently more accurate prices"; and a continuing struggle to obtain accurate pricing from pharmaceutical manufacturers with respect to their drug products. (CA SOAF Defs. ¶ 11.) Professor Marmor makes clear that establishing reimbursement policy is not as simple as the Defendants suggest. Additionally, as one might suspect, the Program relies upon the accuracy of the information provided by all stakeholders, and establishing appropriate rates is made all the more difficult, expensive, and time consuming when the prices California relies upon to establish such rates are fraudulent. (CA SOAF Defs. ¶¶ 12-14.) Indeed, had Defendants reported reasonable AWPs, the five hundred thousand dollars and hundreds of hours Medi-Cal expended on the Myers & Stauffer reports could have instead been used to improve health care delivery to the State's disadvantaged. (CA SOAF Defs. ¶¶ 13-14.)

5. Defendants' Claim that Medi-Cal Ratified Defendants' Fraudulent Reporting of False AWPs is Meritless.

Unable to justify their malfeasance, Defendants are left with the impossible task of seeking to justify their deliberately inflated AWPs, after the fact, by shifting the blame to Medi-

Cal for complying with California statutory and regulatory authority by relying on those AWPs. Defendants suggest that when California ultimately made changes to its prescription drug reimbursement rate in 2002, and then again in 2004, it reduced reimbursements by less than the 40% discount from AWP that Myers & Stauffer recommended as appropriate for generics, or even the 20% discount that DHCS originally suggested in 2004. (Defs. Jt. SJ Br. 11-12) Defendants then simply speculate that these changes must have been the result of striking a compromise between competing interests of economy and access, as required by Section 30(A)—i.e., that California must have deemed Defendants' fraudulent AWPs to be acceptable under the circumstances. This is the *post hoc ergo propter hoc* fallacy that Defendants have promoted since the inception of this action. Nothing in the record before the Court even remotely suggests that California's adjustments of its prescription drug reimbursement rate from AWP-5% to AWP-10% in 2002, and from AWP-10% to AWP-17% in 2004, was in any way a ratification of Defendants' submission of false and inflated AWPs.

Indeed, the evidence affirmatively demonstrates that California never ratified Defendants' publication of false and inflated AWPs. Former Chief Deputy Director for Health Care Services Stan Rosenstein testified that it has never been the policy of the Medi-Cal program to deliberately accept inflated and inaccurate AWPs in order to cross-subsidize the amount of the filling fee for pharmacists, or because it might be able to offset the effect of inflated AWPs with rebates. (CA SOAF Defs. ¶ 15.) According to Mr. Rosenstein, it was always Medi-Cal's policy to seek accurate information and to use that information to establish what the accurate reimbursement amount should be with respect to both ingredient costs and dispensing fees. (*Id.*) It was never the policy of Medi-Cal to accept false information reported by drug manufacturers. (*Id.*)

With regard to Defendants' suggestion that the California Legislature ratified Defendants' grossly inflated AWPs, Mr. Rosenstein makes clear that not only did he never hear a legislator or legislative staffer in either house of the California Legislature express an acceptance of inflated or untruthful AWPs, but that he had heard rather just the opposite—a strong objection to the government receiving false information. (CA SOAF Defs. ¶ 16.) Moreover, the very "Fact Sheet" relied upon by Defendants states the reasons that California reduced its reimbursement rate to AWP-17% (rather than AWP-20% as originally proposed), and further states the fact that the program intended to deal with the problem of inflated generic spreads through a revised MAIC program rather than with a different reimbursement rate. (CA SOAF Defs. ¶ 23.)

Defendants' argument conspicuously ignores, again, the obvious fact that Defendants and their false AWPs were the basis for the inflated prescription drug market to begin with. Mr. Rosenstein testifies that had the manufacturers truthfully reported accurate pricing, Medi-Cal would have been able to maintain an accurate reimbursement system that would have enabled it to pay pharmacies using accurate prices. (CA SOAF Defs. ¶¶ 12-14.) Consequently, had Defendants simply been honest about their AWPs, Medi-Cal could have saved the taxpayers hundred of millions of dollars, and would not have been required to come up with alternative methods in an attempt to collect honest data from the manufacturers. (*Id*.)

Finally, the allegation that California did not act in response to the allegations in VAC's Amended Complaint is also flawed, both legally and factually. Medi-Cal was not required to restructure its large and complex pharmaceutical reimbursement system—which, on the whole, worked reasonably well—in order to deal with the fraudulent efforts of a handful of industry participants to game that system. Rather, California acted appropriately in response to the

Amended Complaint—by thoroughly investigating the allegations and intervening as to select defendants (such as Dey, Mylan, and Sandoz) whose behavior, as to certain drugs, was especially egregious and harmful. In that context, Defendants' Motion should be seen for what it is: just one more effort to frustrate the appropriate efforts of California officials to fix the system and remedy prior misconduct.

Each adverse consequence of Medi-Cal's use of, and reliance on, inflated AWPs and their related spreads ultimately finds its way to Defendants' doorstep. That Medi-Cal consistently, repeatedly, and doggedly sought to make adjustments to its drug reimbursement rates, even if imperfectly, in no way justifies or excuses Defendants' malfeasance. Nor does it come close to demonstrating that California in any way approved of or ratified Defendants' conduct.[7]

II. CALIFORNIA'S FCA CLAIMS REMAIN VALID AFTER THE AUGUST 2002 MYERS & STAUFFER REPORTS.

Defendants argue without merit that California's claims "are barred in their entirety as a matter of law at least as of August 2002," when California obtained the Myers & Stauffer reports regarding pharmacists' drug acquisition costs and dispensing costs. Defendants' argument is based on two fundamentally erroneous assumptions. First, Defendants assume that the Legislature's failure *to immediately* change the reimbursement system in response to the Myers & Stauffer reports signals the State's approval of their mega-spreads. That assumption is wholly unwarranted; indeed, it is belied by the fact that the Legislature substantially revised Medi-Cal pharmaceutical reimbursement rates in 2004 in accord with the Myers & Stauffer reports.

[7] Defendants' glancing reliance on the Alabama Supreme Court's decision in *AstraZeneca L.P. v. State*, No. 1071439, 2009 WL 3335904 (Ala. Oct. 16, 2009) is misplaced. The findings of the Alabama high court concerning its understanding of the facts particular to an Alabama common law fraud case concerning branded drugs with spreads well within the "Hartman Speed-Limit" (approved by this Court, and later approved (as it was applied by this Court) in the First Circuit in *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 582 F.3d at 180-184), has little to offer the Court with respect to this case, which concerns a California false claims action focused on specific generic drugs with spreads as high as 7685%.

Second, Defendants assume that California was required to revamp its pharmaceutical reimbursement system in order to correct their mega-spreads and that, by failing to act, the State "intentionally adopted reimbursement methodologies that would pay these so-called 'mega-spreads' for its own policy reasons…." (Defs. Jt. SJ Br. 21.) Contrary to Defendants' assumption, however, one cannot attribute intent to the tardiness or failure of government entities to act. Finally, Defendants are factually wrong in asserting that California failed to attempt to correct the large spreads on their generic drugs. California attempted to address that problem in the 2004 legislation and, having been frustrated in that effort by Defendants, has taken further steps since then.

A. The Government Knowledge Defense Under California Law Requires Government Approval of the Conduct After Full Disclosure of the Relevant Facts By Defendants, Neither of Which Has Been Shown Here.

As more thoroughly explained in Plaintiffs' Opposition to Defendant Dey's Motion for Partial Summary Judgment, and contrary to Defendants' argument, government officials' knowledge of a fraud, without more, does not "negate the fraud or falsity that is required by the" CA FCA. Defs. Jt. SJ Br. at 22, *citing American Contract Services v. Allied Mold & Die, Inc.*, 94 Cal. App. 4th 854, 864 (2001). Defendants succeed with such a defense *only* when that government knowledge is accompanied by affirmative approval of the underlying behavior by authorized government officials. Defendants fail to make that showing.

B. Any Arguable Knowledge On the Part of Agency Personnel Cannot Negate Falsity or Scienter Where, as Here, The Claims Arise From Violations of a Non-Discretionary Regulatory or Statutory Standard.

Defendants' "intervening event" causation arguments and their government knowledge arguments rest on the same diaphanous theory: California knew of, and approved, the nature of the AWPs that Defendants reported in order to cross-subsidize allegedly inadequate dispensing

fees and encourage the use of generic products. To succeed, Defendants must show that Medi-Cal authorized Defendants to report inflated AWPs. *See generally, United States ex rel. A+ Homecare, Inc.*, 400 F.3d at 454 n.21 ("defendant's conduct may not be actionable if what the defendant submitted was not actually false but rather conformed to a modified agreement with the Government"); *United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1157 (2d Cir.), *cert. denied*, 508 U.S. 973, 125 L. Ed. 2d 663, 113 S. Ct. 2962 (1993) (government knowledge may be relevant to "show that the contract has been modified or that its intent has been clarified, and therefore that the claim submitted by the contractor was not 'false'"). Where the governing standard exists in a statute, there must be an actual amendment to the governing statute. As the Supreme Court has stated, "'Congress may legislate … only through the passage of a bill which is approved by both Houses and signed by the President. See U.S. Const., Art. I, § 7, cl. 2. Congressional inaction cannot amend a duly enacted statute.'" *Patterson v. McLean Credit Union*, 491 U.S. 164, 175, n. 1 (1989) [citation omitted], *superseded by statute on other grounds as stated in CBOCS West, Inc. v. Humphries*, ___ U.S. ___, 128 S. Ct. 1951, 1956-57 (2008); *see Helvering v. Hallock*, 309 U.S. 106, 121, 60 S. Ct. 444 (1940) (Frankfurter, J.) ("We walk on quicksand when we try to find in the absence of corrective legislation a controlling legal principle"); *Pension Benefit Guaranty Corporation v. LTV Corp.*, 496 U.S. 633, 650 (1990) ("Congressional inaction lacks persuasive significance because several equally tenable inferences may be drawn from such inaction, including the inference that the existing legislation already incorporated the offered change.") (internal quotation marks omitted).

In interpreting a statute, courts normally follow the plain meaning of the legislative language. Extraneous evidence outside official legislative materials is not considered. Hence,

"[m]aterial showing the motive or understanding of an individual legislator, including the bill's author, his or her staff, or other interested persons, is generally not considered." *Metropolitan Water Dist. v. Imperial Irrigation Dist.*, 80 Cal. App. 4th 1403, 1426 (2000); *Quintano v. Mercury Casualty Co.*, 11 Cal. 4th 1049, 1062 (1995). "This is because such materials are generally not evidence of the Legislature's collective intent." *Williams v. Garcetti*, 5 Cal. 4th 561, 569 (1993).

In the regulatory context, courts have consistently held that there is a high degree of formality required for an agency statement to constitute an expression of policy or a compelling interpretation of a regulation. The California Supreme Court addressed this issue quite recently, in *Miller v. Bank of America, NT & SA*, 46 Cal. 4th 630 (Cal. 2009). The court in *Miller* analyzed "an interpretation contained in an opinion letter, not one arrived at after, for example, a formal adjudication or notice-and-comment rulemaking." *Id*. at 644. The court concluded that "[i]nterpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law—do not warrant … deference." *Id. See also de la Hoya v. Top Rank, Inc.*, 2001 WL 34624886 *11 at fn 8 (C.D. Cal. 2001) ("the affidavit of a staff member of a regulatory agency is entitled to little weight where it is individual rather than institutional in origin and does not issue from official agency action").

That is consistent with Federal law. As the First Circuit has held:

> The non-public or informal understandings of agency officials concerning the meaning of a regulation are thus not relevant. The affidavits here of former and present agency officials as to the agency's non-public understanding of the regulation do not remotely satisfy the requirements of formality and public accessibility. The statements made by government officials at industry seminars (upon which the defendants also rely), although public, are also not the kind of formal agency statements that are entitled to deference.

United States v. Lachman, 387 F.3d 42, 54-55 (1st Cir. Mass. 2004). *See Environmental Defense Fund v. Duke Energy Corp.*, 549 U.S. 561, 580-81 (2007) ("An isolated opinion of an agency official does not authorize a court to read a regulation inconsistently with its language"); *Crude Co. v. Federal Energy Regulatory Comm'n*, 135 F.3d 1445, 1452 (Fed. Cir. 1998) ("[T]he informal views of agency lawyers, like the views expressed in internal documents, are not binding on the government.").

Nor does the argument that the regulation or statute at issue has not been effective in accomplishing its purpose permit a court to read in a different meaning. This issue was recently addressed in the context of a job training program, where plaintiff—as Defendants do herein—attempted to convert a legal issue of statutory interpretation into a referendum on the wisdom or efficacy of the program. The court's dismissal of this argument is instructive:

> Watkins's efforts to address this concern expose the weakness of his position. For the most part, Watkins argues as a factual matter that the county has failed to provide meaningful job assistance and training to persons deemed employable. The suggestion appears to be that the programs the county has adopted would not aid persons deemed "unemployable," even if they were allowed or required to participate in them. However, the issue is legal and not factual in nature. The point is that the statute evinces a Legislative intent to link job training to the availability of GA benefits for employable persons. This intent is inconsistent with the notion that persons lacking skills and therefore most in need of job training would not qualify as employable individuals entitled to job training. *For purposes of assessing legislative intent, it is irrelevant that the county's job training efforts may have been less than successful as a factual matter.*

Watkins v. County of Alameda, 177 Cal. App. 4th 320, 341-342 (2009) (emphasis added).

Without question, there are internal documents originating in Medi-Cal's pharmaceutical reimbursement program, as well as in the public regulatory and statutory history, showing that various individuals expressed concerns with matters, including the prices of drugs, the reported

prices of drugs, the need to ensure pharmacy participation in the Medi-Cal program, the possible benefits of incentivizing pharmacies to dispense generic drugs (or to simply require generic substitution), the varying cost structures of different pharmacies across the State, the lack of available information about actual costs for drugs, the need to encourage physicians to prescribe lower cost drugs, the possible use of drug management programs to regulate use of expensive drugs, and the use of per patient caps on brand drugs. There are also more direct references to differences between invoice prices and reported AWPs, sometimes focused on generic drugs in particular and often remarking on the large discrepancies between reported and actual drug prices. But this discussion—which was always set against the backdrop of a reimbursement system that was federally mandated to reimburse based on estimated acquisition costs, and was consistently designed by California to accomplish that purpose—cannot reasonably be read as anything other than an ongoing effort by the State to rein in its costs and properly set reimbursement rates so as to ensure access and pay reasonable amounts for drug products. The expenses involved in this effort were severely hampered by Defendants' deliberately inflated AWPs.

Minnesota Ass'n of Nurse Anesthetists v. Allina Health System Corp., 276 F.3d 1032 (8th Cir. 2002), also provides useful guidance. In that case, the relator sought summary judgment for anesthesiologists' false representations in claims that they had personally performed certain Medicare-covered services. "The defendants introduced evidence that at least some of them relied on [a HCFA] memo [that had been disseminated to them] in forming the belief that they could bill for personally performing cases despite leaving the operating room, so long as they were present in the operating suite, which they define as the area in the hospital where surgery takes place." *Id* at 1054. Any ambiguity from this HCFA memo was cleared up after about six

months, but the billings continued. The appellate court reversed the district court's ruling that plaintiff had not properly shown scienter, holding that the range of deviations from "personal performance" extended far beyond what might have been excused by the HCFA memo, specifically, absence for extended periods of time from the operating suite or even the hospital, unavailability during emergencies, and contemporaneous performance of other tasks inconsistent with personal performance of the claimed anesthesiology services. *Id*. at 1055-56. As the court stated, "Defendants have certainly made no showing that they were led to believe that the kind of conduct outlined above qualified as the personal performance of an anesthesia case." *Id*. at 1056.

This Court rejected a similar argument that some leniency in administrative policy could be deemed government approval of a far broader range of conduct than what was tolerated. In *United States ex rel. Loughren v. Unumprovident Corp.*, No. 03-11699-PBS, 2008 WL 4280133 (D. Mass. Sep. 15, 2008), defendants argued that the Social Security Administration's "open door" policy, which encouraged persons who were unsure about their eligibility to apply for benefits and receive an actual determination, did not excuse the knowing conduct of an insurance company that encouraged individuals to submit claims for which the insurance company *knew* there was no eligibility. This Court ruled that "an open door to claimants who are unsure that they are eligible does not exonerate an insurer that knowingly causes ineligible insureds to apply as part of a fraudulent course of conduct. *Id*. at *2. In other words, the government's approval must specifically and affirmatively ratify the challenged conduct that defendants later try to shield from liability.

In the case at bar, Defendants doggedly spotlight a resigned tolerance by Medi-Cal for a modest cushion in ingredient cost reimbursement, but Defendants have made no showing that they were ever told by anyone that the fraudulently inflated AWPs at issue in this case qualified

as the truthful prices California expected. As this Court and the First Circuit have found, the government "could not have intended AWP to be a term of art for whatever price the industry chose to put in the industry publications" for that would "give the pharmaceutical industry free reign over drug pricing." *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 582 F.3d at 170.

Furthermore, unlike the anesthesiologists in *Minnesota Ass'n*, Defendants conspicuously fail to demonstrate that anyone within their corporate structure had any knowledge of the extensive regulatory record that Defendants now claim somehow justifies their false prices. Defendants' Statements of Fact do not contend that the government record was known to them or relied upon in setting, maintaining or reporting their AWPs. And nothing in Defendants' papers supports that proposition. Defendants are incapable of showing that their price-reporting conduct was not false on the grounds that the government fully understood their opaque pricing manipulation.

III. CALIFORNIA HAS ESTABLISHED CAUSATION OF DAMAGES FOR ANY CLAIM THAT WAS PAID ON THE BASIS OF A FUL.

Defendants claim they are entitled to summary judgment because there is, allegedly, no causal connection between their reported prices and the Federal Upper Limits ("FULs") set by the Centers for Medicare and Medicaid Services ("CMS"); and because Medi-Cal's payments for their drugs paid under a FUL were not "overpayments" since California allegedly could not have, and allegedly did not, pay claims at less than the FUL. (Defs. Jt. SJ Br. 26-29.) Like the others, these arguments also fail.

A. There is a Causal Nexus Between Defendants' Reported Prices and the Damages Incurred by Medi-Cal When it Paid Claims Involving Defendants' Drugs Which Were Set By a FUL.

Defendants continue to argue, as in other cases before this Court, that they are not liable for any damages resulting from provider payments for their drugs that were based on any price other than a published compendia price. Defendants support this argument by attacking the procedures by which CMS set FULs, assuming that if they can discredit CMS's system for setting FULs, they can escape liability for reporting prices which, *inter alia*, scotched the accuracy of the price arrays used by CMS in setting the pertinent FULs. More specifically, Defendants claim that FULs were "set on an *ad hoc* basis." (Defs. Jt. SJ Br. 28.)

First, while Plaintiffs' position on damages as to claims paid at a FUL is straightforward, Defendants seem obtusely determined to disavow any understanding of Plaintiffs' position, notwithstanding repeated explanations regarding Medi-Cal damages as to FUL-paid claims. All of the Subject Drugs were reimbursed based on AWP, FUL or Usual and Customary ("U&C"), under California's "lowest of" reimbursement formula. As the State's statutorily defined "lesser of" formula provides (*see* CAL. WELF. & INST. CODE § 14105.45), AWP is an integral component of the adjudication formula for every single claim at issue in this case. When Defendants published false AWPs, they ensured that any provider claims seeking reimbursement for Defendants' drugs would also be false, if the reimbursement methodology had any linkage to those false AWPs. This necessarily includes any and all instances in which the but-for "real" AWPs calculated by Plaintiffs' damages expert, Dr. Leitzinger, were less than the FUL or U&C on which such claims were paid. In other words, had Defendants reported AWPs that reasonably reflected providers' acquisition costs, those AWPs would have controlled the payment level in all instances in which they were less than the FUL or U&C. Defendants' false AWPs were

therefore material to all instances in which California reimbursed a claim based on the reported AWPs; and were also material to all claims paid by Medi-Cal when the underlying NDC's actual but-for price, if it had been truthfully reported as the AWP, was lower than the FUL or U&C on which the claim was paid.

Second, Defendants are wrong in claiming CMS was inconsistent in the manner in which it set FULs. CMS largely relied on manufacturer WACs in setting FULs, and did so unless a particular WAC was so low that officials determined it was a data "outlier" and therefore an unreliable basis on which to set the FUL. (CA SOAF Defs. ¶¶ 26-28.) CMS manually intervened under just two limited circumstances, both of which removed data errors or inconsistencies so as to ensure the FUL setting process operated properly. (CA SOAF Defs. ¶ 33.) Of course, CMS never used AMPs to set FULs, because AMPs were at the time confidential, and were not readily accessible or published in the national pricing compendia. (CA SOAF Defs. ¶ 26.)

B. California Sometimes Reimbursed Providers in Payments Which Were Less Than the FUL.

Defendants argue that Medi-Cal's payments for their drugs paid under a FUL were not "overpayments" because California could not have, and did not, pay claims at less than the FUL. (Defs. Jt. SJ BR. 28-29.) This speculative assertion is accompanied by no evidentiary support—which is not surprising, because it is entirely false.

First, as explained above, Defendants' false AWPs are demonstrably material to all instances in which California reimbursed a provider claim based on those false AWPs. This includes all claims paid by Medi-Cal when the underlying NDC's actual "but-for" price (if it had been truthfully reported as the AWP), would have been lower than the FUL or U&C on which the claim was actually paid.

Second, the fatuous assertion that California could not "afford" to operate Medi-Cal if it paid claims at less than the FUL (because, Defendants claim, it would run into diminished access problems) is undercut by the historical record embodied in the paid claims for the Subject Drugs, and the Myers & Stauffer reports. Within the universe of 28,695,253 paid claims for the Subject Drugs that fall within in the relevant time period in California's case, there were occasions—at least 312,000 of them—when California paid claims for Defendants' Subject Drugs based on a reported AWP which was, in fact, less than the FUL. There were another 62,000 occasions when California paid claims for the Defendants' Subject Drugs below the FUL and based on the provider's reported Usual and Customary cost. (CA SOAF Defs. ¶¶ 30-31.) The Myers & Stauffer reports, moreover, clearly document the fact that "[f]or individual [generic] drug products, [provider] acquisition cost as a percent of the FUL was a weighted average of 38.7% of the FUL price." (Robben Decl. Ex. 34 at 23 (CAAG/DHS0068593).)

CONCLUSION

For the reasons set forth above and in Plaintiffs' three Defendant-specific Opposition Briefs, Plaintiffs respectfully request that the Court deny Defendants' joint and individual motions for partial summary judgment.

Dated: December 21, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on December 21, 2009, a copy to Lexis-Nexis for posting and notification to all parties.

/s/ Nicholas N. Paul
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